

REMARKS

Applicants have developed a device for both collecting and drying a liquid biological sample at a first location, and then mailing the dried sample to a clinical laboratory remotely located from the first location for analysis. A preferred version of applicants' device includes a strip having a handle end and a collection end. The collection end has attached thereon a collection pad for collecting and drying a liquid biological sample containing the analyte. The collection pad is made of sponge-like polyvinyl alcohol. This sponge-like polyvinyl alcohol is advantageous in its ability, relative to other materials, to absorb and dry large quantities of a liquid sample (e.g., urine). It is also advantageous in that it is substantially non-reactive and compatible with a blocking agent such as BSA. In comparison to other materials, these advantages allow the sponge-like polyvinyl alcohol to be used for the measurement of a very dilute analyte in a liquid biological sample (e.g., microalbumin in urine).

Rejection Under 35 USC 103 In View Of Bahl

In the Office Action, claims 1, 4, 7, 8, 10, 19, 21, 22 and 24-26 were rejected under 35 U.S.C. 103(a) as being "anticipated by" (applicants assume the examiner intended "unpatentably obvious over") U.S. Patent 5,609,160 to Bahl et al ("Bahl"). The claims as amended herein recite a collection pad either being or consisting essentially of a sponge-like material made of polyvinyl alcohol. Bahl does not teach or suggest a collection pad including a sponge-like material made of polyvinyl alcohol.

Rejection Under 35 USC 103 In View Of Bahl And Chandler

The Office Action rejected claims 5, 11, 12, 20 and 23 under 35 U.S.C. 103(a) as being unpatentable over Bahl and further in view of US patent 6,165,416 to Chandler ("Chandler"). Claims 5, 11, 12, 20 and 23 will be cancelled upon entry of this amendment.

Rejection Under 35 USC 103 In View Of Bahl And May

The Office Action also rejected claims 2, 3, 6, and 9 under 35 U.S.C. 103(a) as being unpatentable over Bahl and further in view of US patent 5,656,503 to May et al ("May"). Claims 2, 3, 6, and 9 will be cancelled upon entry of this amendment.

In this section, the Office Action implied (but did not clearly state) that claims 27-42 were rejected over the combination of Bahl and May. In particular, the Office Action stated:

With respect to claims 27-42, Applicants' invention is further directed to the use of polyvinyl alcohol as the absorbent material. May et al '503 teaches a test device for detecting analytes in biological samples, such as urine, comprising a hollow casing containing a porous carrier and a bibulous receiving member. At col. 9, lines 45-48, May et al '503 teaches the use of blocking reagents such as BSA (albumin) and polyvinyl alcohol for blocking excess binding sites in each zone of the test device. Thus, it would have been obvious to one of ordinary skill in the art to incorporate such reagents into the device of Bahl et al '160 where the blocking of such binding sites is necessary.

Claim 27, from which claims 28-42 depend, recites a collection pad that consists essentially of a sponge-like material made of polyvinyl alcohol. Nowhere in Bahl or May is there taught a collection pad including a sponge-like material made of polyvinyl alcohol. As the Office Action points out, May refers to the treatment of a porous material with polyvinyl alcohol to block binding sites on the material. The form of the polyvinyl alcohol is not indicated to be a

"sponge-like material." Accordingly, applicants' claimed collection pad made of a polyvinyl alcohol sponge-like material is not the same as or even similar to May's porous material treated with polyvinyl alcohol. Moreover, unlike in applicants' claimed invention, May's device does not use polyvinyl alcohol to absorb a sample. Rather May's device uses polyvinyl alcohol to achieve an opposite effect-i.e., to prevent absorption or adsorption of substances to the porous material. Thus because the combination of Bahl and May does not (1) teach a sponge-like material made of polyvinyl alcohol or (2) suggest the desirability of using of a collection pad made of such sponge-like polyvinyl alcohol material for any reason, the presently claimed invention is patentable over this combination of references.

Conclusion

Entry of this amendment would put the current claims in condition for allowance or in better condition for appeal. The amendment presented herein would revise the form of the claims, but would not raise additional substantive issues. Thus, no new matter would be entered by the amendment. Accordingly, entry of the amendment, and reconsideration and allowance of the claims is respectfully requested.

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment of fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 50-0951.

The examiner is invited to call the undersigned if clarification is needed on any matter within this amendment, or if the examiner believes a telephone interview would expedite the

prosecution of the subject application to completion.

Respectfully submitted,

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